Surgeon General NOTAM
RISK MANAGEMENT LESSONS

30 July 1999

The following message is released by the Air Force Medical Operations Agency, and (AFMOA/SGOP) to disseminate critical guidelines for reporting vaccine related adverse events

ATTENTION:
THE FOLLOWING IS AN OFFICIAL SG NOTAM PLEASE PRINT, READ, AND DISSEMINATE TO ALL MEDICAL TREATMENT FACILITY PERSONNEL.

99-005: VACCINE ADVERSE EVENTS REPORTING SYSTEM

In order to employ maximum use of the Vaccine Adverse Events Reporting System (VAERS), the following instructions are to be implemented immediately. This policy supersedes the guidance referenced in the *Tri-Service Reportable Events Guidelines and Case Definitions ver.1.0 July 1998*. This policy provides supplementary information to current guidelines furnished in AFJI 48-110 *Immunizations and Chemoprophylaxis;* section 12- Adverse Events.

Under no circumstances should a problem a patient believes is associated with a vaccine be taken lightly; a VAERS report should be generated any time a vaccine recipient believes they have a problem related to the vaccine.

A VAERS report **must** be generated when vaccine reaction(s) result in hospitalization or time lost from duty (more than 24 hours). The Military Treatment Facility should file a VAERS Report under any circumstances believed by the patient or provider to be vaccine associated, even though it does not meet the strict criteria stated in AFJI 48-110.

The MTF is responsible for ensuring the forms are filled out accurately and as completely as possible. The MTF can then submit the form for the patient, or the patients can submit the form on their own. If the MTF submits the form for the patient, review the form with the patient prior to submission.

Although it is preferable for a provider to fill out a VAERS form, a patient can submit their own VAERS report. If a patient requests a Form VAERS-1 it should be provided to that individual. The patient can be directed to call 1-800-822-7967 (the number on the face of the form) for additional information, or direct them to the web site http://www.fda.gov/cber/vaers/vaers/htm to get additional information.

The instructions for completing the Form VAERS-1 along with a copy form have been included with this NOTAM as an Attachment.

Do not submit adverse events through the Military Immunization Tracking System (MITS) or any other electronic reporting mechanism! All reports of vaccine adverse events must be **mailed within seven days of the occurrence.** A Form VAERS-1 should be submitted to the Food and Drug Administration's (FDA) Vaccine Adverse Events Reporting System and to the Force Health Protection and Surveillance Branch IERA/RSRH (see addresses below). Copies are also provided to the local Pharmacy and Therapeutic Committee, MAJCOM Clinical POC and Air Force Medical Operations Agency (AFMOA). If the incident is life threatening or death has occurred, the report will be made within 24 hours to IERA/RSRH. These reports are consolidated monthly into Defense Medical Surveillance System (DMSS).

For Anthrax Vaccine

IERA/RSRH will submit a supplemental form, specifically for use with adverse anthrax vaccine events to verify completeness and to classify each Form VAERS-1. Both the Form VAERS-1 and the supplemental form should be submitted to the Army Medical Surveillance Activity (AMSA), U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM). The AMSA will coordinate results of these reports directly with DoD AVIP Agency, Office of the Surgeon General (OTSG) and the Service Surgeons General.

Food and Drug Administration (FDA)
Vaccine Adverse Events Reporting System (VAERS)
P.O. Box 1100
Rockville, MD 20849-1100

Force Health Protection and Surveillance Branch
IERA/RSRH
2513 Kennedy Circle,
Brooks AFB, TX 78235-5123,
DSN 240-3471 (commercial: 210-536-6841)

Air Force Medical Operations Agency /SGOP
110 Luke Avenue Room 405
Bolling AFB, DC 20332-7050

My point of contact is Major Pegues, AFMOA/SGOP, DSN 297-4216. This SG NOTAM is posted under "Hot Issues" on the at Prevention Division web page at http://sg-www.satx.disa.mil/moasgop/index/htm

Guidance for Industry

How to Complete the Vaccine Adverse Event Reporting System Form (VAERS-1)

Comments and suggestions regarding this document may be submitted at anytime to Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. For questions regarding this document, contact Dr. Marcel Salive, CBER, Division of Biostatistics and Epidemiology (HFM-220), (301) 827-3974.

Additional copies are available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at http://www.fda.gov/cber/guidelines.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
September 1998

I. INTRODUCTION

This guidance for industry has been developed to clarify what information should be obtained before an individual case of an adverse experience after immunization should be submitted to the Vaccine Adverse Event Reporting System (VAERS). The Food and Drug Administration (FDA) believes that the recommendations in this guidance document will improve the quality of postmarketing safety reports and clarify the industry's current safety reporting responsibility to assure public health.

This guidance document should be used in conjunction with the Center For Biologics Evaluation and Research (CBER's) Guideline for Adverse Experience Reporting for Licensed Biological Products (October 1993) and, ultimately, with any future guidance that supersedes the October 1993 guideline. Hard copies of the guidances are available from CBER's Office of Communication, Training and Manufacturers Assistance (address above). Electronic versions of these guidances are also available on the Internet at http://www.fda.gov/medwatch/report/mfg.htm.

1

---

[1] This guidance has been prepared by the Epidemiology Branch in the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. This guidance represents the Agency's current thinking on reporting of certain postmarketing adverse experiences for licensed vaccines. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

[2] For purposes of this guidance, the term licensed manufacturer includes manufacturers, packers, distributors, shared manufacturers, joint manufacturers, or any other participant involved in divided manufacturing.

II. GENERAL INSTRUCTIONS

Licensed manufacturers 2 of approved vaccines are required to report adverse experiences to the FDA under 21 CFR 600.80. These instructions for completing form VAERS-1 are for use by manufacturers for mandatory reporting of adverse events as designated in the applicable statutes and FDA regulations.

° All entries should be typed or printed in a font no smaller than 10 point
° All boxes should be completed
° To complete an item when information is not available, use:
    ° **NA** for not applicable
    ° **NI** for no information at this time (but may become available later)
    ° **UNK** for unknown
° Dates should be entered as month, day, and year, formatted as MM/DD/YYYY (e.g., June 3, 1997 = 06/03/1997). If exact dates are unknown, provide the best estimate. If day is unknown, month and year is acceptable. If day and month are unknown, year is acceptable.
° Times should be reported as hour: minute (hh:mm) with AM or PM specified. If exact time is unknown, estimate AM or PM, if possible.
° For narrative entries, if the fields do not provide adequate space, attach an additional page(s). The following specific information is to be incorporated:
° Identify all attached pages as Page __ of __ using the page number and total
° Indicate the appropriate box number and field name next to the narrative continuation
° Include the phrase continued at the end of each field that has additional information continued onto another page
° Display the Manufacturer report number (see box 24) in the upper right corner of each page, with the VAERS identification number, if known, for follow-up reports.
° Include the firm's name in the upper right corner, if the report is from a distributor or manufacturer
Submission of the front of the form only is acceptable **.**

III. SPECIFIC INSTRUCTIONS (refer to attached Form VAERS-1)

Patient Name - Provide the patient's full name (last name, first name, middle initial). Information identifying the person who received the vaccine or that person's legal representative is required by the National Childhood Vaccine Injury Act and will not be made available to the public.

    ° **Complete a separate form for each patient**

N.B.: When a newborn baby is found to have a congenital anomaly that the initial reporter considers possibly associated with a vaccine administered to the mother during pregnancy, the patient is the newborn baby.

Parent-child/fetus report(s) are those cases in which either a fetus/suckling infant or the mother, or both, sustain an adverse event that the initial reporter considers possibly associated with a vaccine administered to the mother during pregnancy. Several general principles are used for filing these reports:
° If there has been NO event affecting the child/fetus, report ONLY on the parent
° For those cases describing fetal demise or early spontaneous abortion, ONLY a parent report is applicable
° When ONLY the child/fetus has an adverse reaction/event (other than early spontaneous abortion/fetal demise), the information in **boxes 3, 4, 5, 11, 22 and 23** applies to the child/fetus, and characteristics concerning the parent who was the source of exposure to the vaccine is to be provided in **boxes 10, 13, 14, 17, and 18.**
° If BOTH the parent and the child/fetus sustain adverse events, two reports should be provided and linked using the narrative (refer to the manufacturer control #'s in box **24)**

N.B.: Submitted VAERS-1 report forms can be obtained under the Freedom of Information

(FOI) Act, with patient and reporter identifying information redacted.
° Thus, when a patient or parent is the reporter, the patient name should be provided in case follow-up might be needed, since such information is NOT releasable under FOI. However, a company can use the term “Consumer-Confidential,” provided that should FDA request to contact that patient, the information would be made available to FDA.

Address - Provide the patient’s current address and telephone number.

Vaccine Administered by - Provide the name of the health care provider who administered the vaccination (not prescribing health care provider, unless it is the same person).

Responsible physician - Name of prescribing or responsible physician in the health care setting where the vaccine was given

Form completed by - Provide the name, mailing address and phone number of the initial reporter (the person who initially reported the adverse event to the manufacturer) who can be contacted to provide information on the event if follow up is necessary. If a report is provided anonymously, so indicate.

1: State - Provide two-letter postal abbreviation for state where vaccine was administered. Use patient’s home state if state where administered is not known. Use “FR” if vaccine was not administered in the United States.

2: County where administered - Provide full name of county where vaccine was administered, if known.

3: Date of birth - Enter the patient's birth date, if known; otherwise enter the patient's age at the time of vaccination in Box 4.

4: Patient age - Provide patient’s age at time of vaccination. Identify units as years, months, or days.
- ° if the patient is **3 years or older**, use **years** (e.g., 4 years).
- ° if the patient is **less than 3 years old**, use **months** (e.g., 24 months).
- ° if the patient is **less than 1 month old**, use **days** (e.g., 5 days).

Provide the best estimate if exact age is unknown. For example, if age can be estimated as 18 years or older, code **AD** for adult; if under 18 years, code **PD** for pediatric.

5: Sex - Check box for the patient’s gender.

6: Date form completed - Enter the date the report is filled out.

7: Describe adverse event(s) - Describe the event in detail using the **reporter's own words**, including a description of what happened and a summary of all relevant clinical information (signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If relevant and available, include synopses of any office visit notes or the hospital discharge summary. To save time (and if permitted by the institution), attach copies of these records.
° Include a list of adverse event terms that most accurately characterizes the adverse event described in this narrative. List the most important terms first. The terminology should be an accepted standard (e.g., Medical Dictionary for Drug Regulatory Affairs (MedDRA) or FDA's Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART)).
° The adverse event should at a minimum consist of signs, symptoms, and/or disease diagnosis. If it is initially known only that a patient “experienced unspecified injury,” active investigation should be conducted to obtain more specific information about the adverse event before it is submitted. The only exception occurs with a fatal outcome, where the FDA expects manufacturers to submit all reports of patient deaths (outcome) even if the causal adverse event is unknown.
° Results of relevant tests and laboratory data should be entered in box 12. Previous and concurrent treatments, pre-existing medical conditions and other relevant history belong in boxes 14, 17, 18, 19. (See instructions for those specific boxes).

8: Check all appropriate - Check all boxes that apply.
Patient Died - Check ***only*** if the death was an ***outcome*** of the adverse event and include the date of death, if known.
Do NOT check if:

- ° the patient happened to die but there was no suspected association between the death and vaccine;
- ° a fetus is aborted because of a congenital anomaly, or is miscarried.

Life-threatening illness - Check if the patient was at substantial risk of dying at the time of the adverse event.

Required emergency room/doctor visit - Check if an emergency room or physician was visited as a result of the adverse event.

Hospitalization (initial or prolonged) - Check if the adverse event resulted in admission to the hospital or prolongation of hospitalization. Note number of days hospitalized.

DO NOT check if:

- ° A patient in the hospital received a vaccine and subsequently developed an otherwise nonserious adverse event, UNLESS the adverse event prolonged the hospital stay

Resulted in permanent disability - Check if the adverse event resulted in a substantial disruption of the person's ability to conduct normal life functions. Such would be the case if the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.

None of the above - Check only if the other categories are not applicable to the report.

9: Patient recovered - Check status of patient at time form was completed. Check "yes" if the patient's health condition is the same as it was prior to the vaccination, "no" if the patient has not returned to the pre-vaccination state of health.

10: Date of vaccination - Provide date of last vaccination before event.

11: Adverse event onset - Provide date and time of onset of event symptoms following vaccination. If more than one adverse event occurred, provide information for the most serious event.

- ° When a newborn baby is found to have a congenital anomaly, the event onset date is the date of birth of the child.
- ° When a fetus is aborted because of a congenital anomaly, or is miscarried, the event onset date is the date pregnancy is terminated.

If information is available as to time during pregnancy when exposure occurred, indicate that information in narrative box 7.

12: Relevant diagnostic tests/laboratory data - Provide all appropriate information, including relevant negative test and laboratory findings, in order to convey most completely how the medical work-up and assessment led to consideration of vaccine as a possible etiology for clinical status, as other differential diagnostic considerations were being eliminated. In addition to providing the laboratory values, identify normal results with **"NL,"** abnormal results with "**ABNL**" or provide the normal range for the laboratory. Standard, unambiguous medical abbreviations should be used; otherwise terms should be spelled out.

Include relevant laboratory data:

- ° Providing baseline prior to the vaccine administration
- ° Used in diagnosing the event
- ° Providing information on the course of the event.

Also include:

° Synopses of any relevant autopsy, pathology, or lab reports
° Pre- and post-event levels of concomitant medication and dates (if applicable, such as for suspected interactions) If preferred, copies of any reports may be submitted as attachments (put a note in this box), with all confidential information deleted.

13: Enter all vaccines given on date listed in item 10 - Enter all known vaccines administered on that date, regardless of presumption of causal relationship to event.

Vaccine (type*)* - Use the abbreviations provided in Appendix A of this guidance. If unknown or if no trade name, use the generic name (with the manufacturer's name if known). For foreign reports, use the foreign trade name and the U.S. generic name.

Lot number - Include the lot number(s) for all vaccines.

Route/site - Describe how the vaccine was administered to the patient (e.g., IM/rt. leg).

No. Previous doses - Indicate the number of previous doses of each vaccine. If event occurred after a series of several vaccinations (e.g., 3 doses of hepatitis B vaccine), give details of prior immunizations in box 14.

Route of Administration	**Code**
Intramuscular	**IM**
Oral	**PO**
Subcutaneous	**SC**
Other	**See Appendix B**

14: Any other vaccinations within 4 weeks prior to the date listed in item 10 - See instructions for box 13. Also include information regarding any previous injections of a vaccine listed in box 13 that were given to *an adult patient* in a series (e.g., 2 prior doses of hepatitis B vaccine).

15: Vaccinated at - Check appropriate box.

16: Vaccine purchased with - Check appropriate box based on how the facility or person who administered the vaccine purchased it, not to payment by the patient's health insurance.
° **Private funds** - purchased by the administering facility with private funds
° **Public funds** - purchased by state or local health department or the Centers for Disease Control and Prevention (CDC)
° **Military funds** - purchased by US military.

17: Other medications - List and provide therapy dates for any other medical products (drugs, biologics, and medical devices) that a patient was using at the time of the event. Include routine medications, prophylactic medications such as over-the-counter (OTC) antipyretics, and medications given before the onset of symptoms. Include tuberculin skin test if given on the date of vaccination. Do NOT include products used to treat the event, which should be reported in Box 7.

18: Illness at time of vaccination - Provide information on any short-term illness, condition or symptom present at or about the time of vaccination (e.g., cold, fever, ear infection).

19: Pre-existing physician-diagnosed allergies, birth defects, medical conditions - If

available, provide information on other known physician-diagnosed medical conditions in the patient (e.g., asthma, seizure disorder, immunosuppression, etc.) and significant historical information (allergies, birth defects, etc.).

20: Have you reported this adverse event previously? - Indicate if the initial reporter has also notified the patient's physician or health department. Check "To manufacturer" if another manufacturer has been notified by initial reporter or by reporting manufacturer. Otherwise leave blank.

21: Adverse event following prior vaccination - List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations, specifying the implicated vaccine, if possible. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain.

22: Birth weight - Provide the patient's birth weight (in pounds and ounces) for children 5 years of age or younger. Current weight, if relevant, should be noted in the narrative (Box 7).

23: No. of brothers and sisters - Provide the number of patient's brothers and sisters, as of the date of vaccination, if the patient is 5 years of age or younger.

24: Mfr/imm. proj. report no. - Provide manufacturer's name and unique identification number for this event. All follow-up reports should have the same number as the initial report.

25: Date received by mfr./imm. proj - Provide the date when the manufacturer received adequate information to determine that the adverse event was reportable; namely that a patient, vaccine, adverse event, and reporter can be identified. For follow-up reports, use the date that the follow-up information was received.

26: 15 Day report? - Check yes if this report meets criteria specified in the biologic regulations for reports of serious and unexpected adverse events (21 CFR section 600.80). If original report did not meet criteria for an expedited report, indicate date that such information was received in narrative summary (Box 7) and/or in cover letter.

27: Report type - Check applicable box.

Initial - check if the report is the first submission of a report.

Follow-up - Check if the report is a follow-up to a previously submitted report.

Follow-up reports should contain information that was submitted in the original report if the information is still correct. If a follow-up report, make sure that the manufacturer report number for the previously submitted initial report has been recorded in box 24.

APPENDIX A: VAERS ABBREVIATIONS FOR VACCINE TYPE

N.B. In addition to vaccines licensed in the U.S., this list includes abbreviations for some vaccines not licensed in the U.S., but which have been the subject of VAERS reports
ADEN Adenovirus Vaccine Live Oral Type 7
ANTH Anthrax Vaccine
BCG BCG Vaccine
CHOL Cholera Vaccine
DT Diphtheria and Tetanus Toxoids Adsorbed Pediatric
DTAP Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Pediatric
DTAPH Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Pediatric and Hemophilus B Conjugate Vaccine
DTIPV Diphtheria and Tetanus Toxoids and Inactivated Polio Virus Vaccine
DTOX Diphtheria Toxoid Adsorbed
DTP Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed Pediatric
DTPH Diphtheria and Tetanus Toxoids and Pertussis and Hemophilus B Conjugate Vaccine Adsorbed Pediatric
DTPIPV Diphtheria and Tetanus Toxoids and Pertussis Adsorbed Pediatric and Inactivated Polio Virus Vaccine
FLU Influenza Virus Vaccine
HBHEPB Hemophilus B Conjugate Vaccine and Hepatitis B Vaccine
HEPA Hepatitis A Vaccine
HEPB Hepatitis B Vaccine
HIBV Hemophilus B Vaccine
IPV Inactivated Polio Virus Vaccine
JEV Japanese Encephalitis virus Vaccine Inactivated
M Measles Virus Vaccine Live
MEN Meningococcal Polysaccharide Vaccine
MM Measles and Mumps Virus Vaccine Live
MMR Measles, Mumps, and Rubella Virus Vaccine Live
MR Measles and Rubella Virus Vaccine Live
MU Mumps Virus Vaccine Live
MUR Rubella and Mumps Virus Vaccine Live
OPV Polio Virus Vaccine Live Oral Trivalent
P Pertussis Vaccine
PLAGUE Plague Vaccine
PPV Pneumococcal Vaccine Polyvalent
R Rubella Virus Vaccine Live
RAB Rabies Vaccine
RSV Respiratory Syncytial Virus Vaccine
SMALL Smallpox Vaccine
TD Tetanus and Diphtheria Toxoids Adsorbed Adults
TTOX Tetanus Toxoid
TYP Typhoid Vaccine
VARCEL Varicella Vaccine Live
YF Yellow Fever Vaccine

APPENDIX B: ROUTES OF ADMINISTRATION LIST AND NUMERIC CODES

Description ICH-M2 Numeric Codes

Auricular (otic) 001
Buccal 002
Cutaneous 003
Dental 004
Endocervical 005
Endosinusial 006
Endotracheal 007
Epidural 008
Extra-amniotic 009
Hemodialysis 010
Intra corpus cavernosum 011
Intra-amniotic 012
Intra-arterial 013
Intra-articular 014
Intra-uterine 015
Intracardiac 016
Intracavernous 017
Intracerebral 018
Intracervical 019
Intracisternal 020
Intracorneal 021
Intracoronary 022
Intradermal 023
Intradiscal (intraspinal) 024
Intrahepatic 025
Intralesional 026
Intralymphatic 027
Intramedullar (bone marrow) 028
Intrameningeal 029
Intramuscular 030
Intraocular 031
Intrapericardial 032
Intraperitoneal 033
Intrapleural 034
Intrasynovial 035
Intratumor 036
Intrathecal 037
Intrathoracic 038
Intratracheal 039
Intravenous bolus 040
Intravenous drip 041
Intravenous(not otherwise specified) 042
Intravesical 043
Iontophoresis 044
Occlusive dressing technique 045
Ophthalmic 046
Oral 047
Oropharingeal 048
Other 049
Parenteral 050
Periarticular 051
Perineural 052
Rectal 053
Respiratory (inhalation) 054
Retrobulbar 055
Subconjunctival 056
Subcutaneous 057
Subdermal 058
Sublingual 059
Topical 060
Transdermal 061
Transmammary 062
Transplacental 063
Unknown 064
Urethral 065
Vaginal 066